

REMARKS

An election requirement was made to pending claims 1-17. The claims were placed into the following two groups: Group I (claims 1-12) drawn to a method of making a solid pharmaceutical composition of perindopril or a salt thereof, comprising dry mixing of perindopril or a salt thereof with at least one inorganic carbonate, at least one carrier, and optional other components, and dry processing of the mixture to the desired solid form; and Group II (claims 13-17) drawn to a composition comprising perindopril or salt thereof, microcrystalline cellulose weight and anhydrous lactose.

In response to this restriction/election requirement Applicant hereby elects the claims of Group II (claims 13-17). For the reasons discussed below Applicant makes this election with traverse and respectfully requests that the Examiner reconsider.

The Examiner has restricted the claims of the instant invention into two groups on the basis that under PCT Rule 13.1 the two groups do not relate to a single inventive concept and under PCT Rule 13.2 the two groups lack the same or corresponding special technical feature. The Examiner identifies the technical feature linking Groups I and II as perindopril and at least one carrier. The Examiner then reasons that Eyjolfsson (WO 03/059388) teaches stable formulations of ACE-inhibitor compounds including perindopril comprising a carrier and excipients and that Bergman *et al.* (GB 2394660) teach formulations of ACE-inhibitor compounds including perindopril comprising excipients which include carriers. From this the Examiner concludes that the technical feature linking the inventions of Groups I and II does not constitute a special technical feature as it lacks novelty.

In response, Applicant notes that this case is a 35 U.S.C. § 371 national phase application of PCT/EP2005/003277 (WO 2005/094793). As such, the Application was subject to Examination by the European Patent Office (as the selected International Searching Authority) and an International Search Report (ISR) and International Preliminary Examination Report (IPER) were issued. A complete copy of each of these documents is attached hereto for the Examiner's ease of reference. With reference to the ISR and IPER, Applicant notes that there was no finding by the International Searching Authority of lack of unity and the claims were determined to be both novel and non-obvious over the art cited which includes the art cited by the Examiner in the instant

application.

As noted in the IPER, the present application discloses a pharmaceutical composition of perindopril or a salt thereof, preferably comprising at least one inorganic carbonate, more preferably comprising indapamide and the production thereof by dry mixing. Eyjolfsson (WO 03/059388), which discloses formulations of ACE inhibitors (perindopril) produced with alkali earth metal carbonates to form stable tablets by the method of wet granulation, was determined to be the most relevant reference cited. As noted by the International Searching Authority this reference does not teach or suggest use of a dry technique to obtain pharmaceutical compositions of perindopril.

On this basis Applicant respectfully requests that the Examiner reconsider and withdraw the finding of lack of unity in the instant case. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefor to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to deposit account No. 19-5117.

Respectfully submitted,

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2005/003277

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, EMBASE, BIOSIS, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/059388 A (DELTA HF; EYJOLFSSON, REYNIR) 24 July 2003 (2003-07-24) the whole document claims 1-11	1-8, 13-15
X	GB 2 394 660 A (* NICHE GENERICS LIMITED; * UNICHEM LABORATORIES LIMITED) 5 May 2004 (2004-05-05) the whole document page 18, line 1 - page 23, line 22; claims 23-62	1-8, 13-15
P, X	WO 2005/011737 A (CIPLA LIMITED; LULLA, AMAR; MALHOTRA, GEENA; WAIN, CHRISTOPHER, PAUL) 10 February 2005 (2005-02-10) the whole document claims 1-45; examples 1,3,7	1-8, 13-15

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

11 August 2005

Date of mailing of the international search report

05/09/2005

Name and mailing address of the ISA

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Felder, C

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No



PCT/EP2005/003277

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03059388	A	24-07-2003	AU 2003235579 A1	30-07-2003
			EP 1513555 A1	16-03-2005
			WO 03059388 A1	24-07-2003
			US 2005118259 A1	02-06-2005
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GB 2394660	A	05-05-2004	NONE	
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WO 2005011737	A	10-02-2005	GB 2404336 A	02-02-2005
			WO 2005011737 A2	10-02-2005
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P 68446		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)
International application No. PCT/EP2005/003277	International filing date (day/month/year) 29.03.2005	Priority date (day/month/year) 29.03.2004
International Patent Classification (IPC) or both national classification and IPC INV. A61K9/20		
Applicant KRKA, TOVARNA ZDRAVIL, D.D., NOVO MESTO et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input checked="" type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 19.01.2006		Date of completion of this report 22.08.2006
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Felder, C Telephone No +49 89 2399-7852 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP2005/003277

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-11 as originally filed

Claims, Numbers

1-17 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP2005/003277

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-17
	No: Claims	
Inventive step (IS)	Yes: Claims	1-17
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-17
	No: Claims	

2. Citations and explanations

see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following document:

D1: WO 03/059388 A (DELTA HF; EYJOLFSSON, REYNIR) 24 July 2003 (2003-07-24)

The present application discloses a pharmaceutical composition of perindopril or a salt thereof, preferably comprising at least one inorganic carbonate, more preferably comprising indapamide and the production thereof by dry mixing.

1. Novelty

The present application does meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-17 is new in the sense of Article 33(2) PCT.

Documents **D1** disclose (citations see ISR) formulations of ACE inhibitors (e.g. perindopril) produced with (alkali-) earth metal carbonate to form stable tablets by the method of wet granulation. Therefore, present claims 1-17 are novel over the prior art **D1**.

2. Inventive step

The present application does meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-17 does involve an inventive step in the sense of Article 33(3) PCT.

The most relevant document **D1** doesn't suggest nor contain any hint to use a dry technique to obtain pharmaceutical composition of perindopril.

Therefore, the present claims 1-17 are inventive in the sense of Article 33(3) PCT.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP2005/003277

3. Industrial applicability

Present claims 1-17 are industrial applicable.